

REMARKS

Claims 1, 7, 9-11, 14-86, 88-90, 93, 95-105, 107-117, 119-127, 129-139 and 141-145 are pending in the present application. Claims 14-84, 96, 107-109, 111-117, 119-121 were previously withdrawn from consideration as drawn to a non-elected invention. Claims 2-6, 8, 12, 13, 87, 91, 92, 94, 106, 118, 128, and 140 were previously cancelled. By virtue of this response, claims 1, 11, 85, 86, 88-90, 97, 98, 127, 130-133, 142, 143, and 145 have been amended. No new claims have been added, and no claims have been cancelled. Accordingly, claims 1, 7, 9-11, 85-86, 88-90, 93, 95, 97--105, 110, 122-127, 129-139 and 141-145 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

Substance of Interview

Applicants thank Examiners Young and Silverman for extending the courtesy of an in-person interview, which was had on March 11, 2010 with Applicants' representatives, Keith Bley, Jane Wright-Mitchell, and Mika Mayer. During that interview, the claims and cited reference were discussed. Specifically, proposed amendments to the independent claims were discussed. The proposed amendments highlight Applicants' claimed invention of a topically administered liquid formulation, comprising between about 6% (w/v) to about 60% (w/v) of a TRPV1 agonist, two different penetration enhancers, and not more than 5% (w/v) of optional additional components, and methods of delivering the same. Examiners Young and Silverman agreed that the proposed amendments would render the claims allowable over the art of record. The proposed amendments have been incorporated into the claims as detailed above and discussed below.

Claim Rejections under 35 U.S.C. §102

Claims 85, 86, 88, 89, 93, 98, 99, 101, 102, 134-136 and 142-145 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Pat. No. 4,599,342 to LaHann et al. ("LaHann"). Applicants disagree with this rejection.

Claims 85 and 86, from which the remaining rejected claims under this section depend, have been amended to recite liquid formulations comprising between about 6% (w/v) to about 60% (w/v) of a TRPV1 agonist (capsaicin in the case of claim 86), at least two different penetration enhancers, and optional additional components comprising not more than 5% (w/v) of the liquid formulation. As discussed during the in-person interview, LaHann fails to teach such liquid formulations.

Accordingly, Applicants respectfully request that the rejections under 35 U.S.C. §102(b) be withdrawn.

Claim Rejections under 35 U.S.C. §103

Claims 1, 7, 9-11, 85, 86, 88-90, 93, 95, 97-105, 110, 122-127, 129-139 and 141-145 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over the combined disclosures of LaHann in view of U.S. Pat. No. 6,299,902 to Jun ("Jun") and U.S. Pat. No. 5,968,539 to Beerse et al. ("Beerse"). Applicants disagree with this rejection.

Claim 1, from which claims 7 and 9-11 depend, has been amended to recite a method of topically applying a liquid formulation to a surface of a mammal, where the liquid formulation comprises between about 6% (w/v) to about 60% (w/v) of a TRPV1 agonist, at least two different penetration enhancers, and optional additional components comprising not more than 5% (w/v) of the liquid formulation. Similarly, claims 85 and 86, from which claims 88-90, 93, 95, 97-105, 110, 122-127, 129-139 and 141-145 depend, have been amended to recite liquid formulations comprising between about 6% (w/v) to about 60% (w/v) of a TRPV1 agonist (capsaicin in the case of claim 86), at least two different penetration enhancers, and optional additional components comprising not more than 5% (w/v) of the liquid formulation.

LaHann was discussed in detail above where it was described how LaHann fails to teach the claimed liquid formulations. Jun, which discloses capsaicin in the context of a melting point depressant, and Beerse, which discloses anti-microbial rinse-off compositions, fail to cure this deficiency.

For at least the above reasons, Applicants submit that a *prima facie* case of obviousness has not been established, and respectfully request that the outstanding rejections of the claims under 35 U.S.C. §103 be withdrawn.

Double Patenting

Claims 85, 86, 88-90, 93, 95 and 97-103 stand provisionally rejected on the ground of non-statutory obviousness-type double patenting as allegedly unpatentable over claims 1, 16, 17, 20, 21, 24, 25, 28, 39-45, 47, 50-54 and 60-63 of co-pending Application No. 11/411,328. Applicants will consider filing a terminal disclaimer after receiving an indication that each of the currently rejected claims is allowable. Until then, Applicants have no real way of assessing the merits of the double patenting rejection or determining whether the filing of a terminal disclaimer is appropriate.

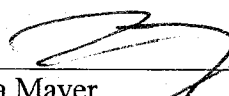
CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 524522001300. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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